Field Safety Notice Reference: FSN 20141212 AMULET

FIELD SAFTY NOTICE

Product: FUJIFILM Digital Mammography System with Biopsy unit
- AMULET (FDR MS-1000)
- AMULET f (FDR MS-2500)
- AMULET Innovality (FDR MS-3500)

Type of Action: Advice regarding use of the device

Dear Customers,

Fujifilm is issuing this Field Safety Notice for all AMULETs with biopsy unit.
This Field Safety Notice is intended to inform you about the following:

- what the problem is
- the actions that should be taken by the customer/user in order to prevent risks to patients;

This document contains important information for the continued safe and proper use of your equipment.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Description of the problem

During a biopsy study using the FUJIFILM Digital Mammography System, it has been found that the User Manual lacks description for handling method for some errors even though the system can be recovered from such errors. If users do not address the recovery procedure properly, there may be an undeniable possibility that the examination is suspended leading to patient re-examination. Thus, the simplified manual* describing the recovery procedure has been created to be distributed to the users who perform a biopsy study.

*Simplified manual; "**Action to Take When an Error Occurs During a Biopsy Study**"

Actions to be taken by customer/user

Read the simplified manual.
When performing a biopsy, keep the simplified manual handy to lower the risk of re-examination.
If any of the following errors occurs, perform the correction procedure in the manual.

(1) Error of the exposure system (Page 2 and following pages in the manual)
(2) Error of the biopsy positioner (Page 8 and following pages in the manual)
(3) Error of the Stereo Biopsy Software (Page 14 and following pages in the manual)

Although the probability of the above errors is very rare, performing the operation according to the manual will lower the risk of requiring re-examination in case such errors occur.

FUJIFILM is committed to providing products and services of the highest quality. Your satisfaction with FUJIFILM products and with our response to this issue is very important to us. If you have any questions about this matter, please contact your local FUJIFILM office.

Yours sincerely,
FUJIFILM

To all FUJIFILM subsidiaries, branch offices and dealers:
PLEASE ENTER YOUR LOCAL CONTACT HERE!

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Customer Feedback Form

Please complete the feedback form as relevant and fax or email it back.
Thank you for your co-operation.

Customer/Facility Name:

Address:

Instrument Serial Number:

☐I confirm that I have received and understand the attached notice.

☐This notice does not apply to my facility.

☐The device has been transferred to another organization.

Customer Name:

Position:

Signature:

Date:

Phone number:

If we have the wrong contact information for you, please correct below:
Customer/Facility Name:

Address:

Please FAX or email this completed form to:
To all FUJIFILM subsidiaries, branch offices and dealers:
FAX: HERE PLEASE FILL OUT
Email: HERE PLEASE FILL OUT